FDA 510(k) Premarket Notification

K061557 FUSION

CLEARED

Sep 15, 2006
102 days to decision

K061557 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k061557/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 5, 2006
Decision date	Sep 15, 2006
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medwave, Inc.**
Location	St. Paul, MN, US
Contact	DONNA R LUNAK
510(k) history	5 submissions · 5 cleared · 1995-2006